(12) UK Patent Application (19) GB (11) 2 028 136 A

(21) Application No 7926599
(22) Date of filing
31 Jul 1979
(23) Claims filed
31 Jul 1979
(30) Priority data
(31) 78/32272
(32) 4 Aug 1978
(33) United Kingdom (GB)
(43) Application published
5 Mar 1980
(51) INT CL³ A61M 25/00
(52) Domestic classification
A5R GE
(56) Documents cited
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GB 1499520
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GB 1121678
GB 1049353
GB 1000078
(58) Field of search
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(54) Improvements in intravascular catheters

(57) Intravascular catheters 1 of flexible plastics or elastomeric material have localised inside the distal tip thereof a radio-opaque metallic component 3.

In order to avoid accidents arising as a result of failure to accurately detect the tip of a catheter a radio-opaque metallic component is localised inside the distal tip of the catheter thereby giving excellent X-ray contrast even when the tip of the catheter is deeply overlaid by tissue. Moreover the catheter retains flexibility which is lost by the use of catheters having braided wire incorporated in the wall thereof.

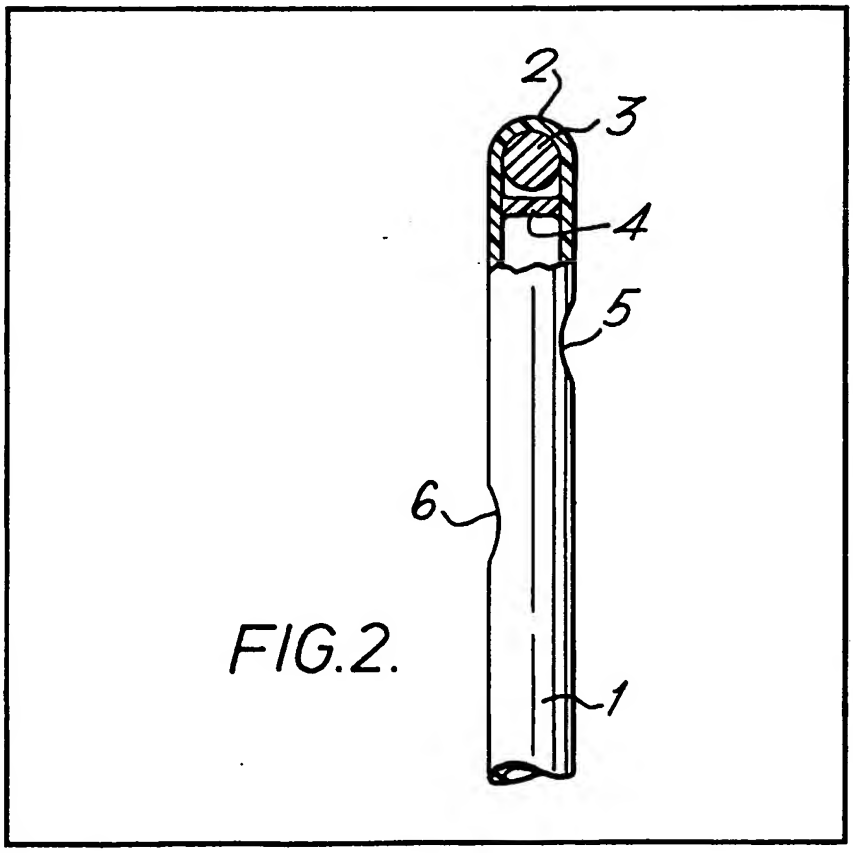

FIG.2.

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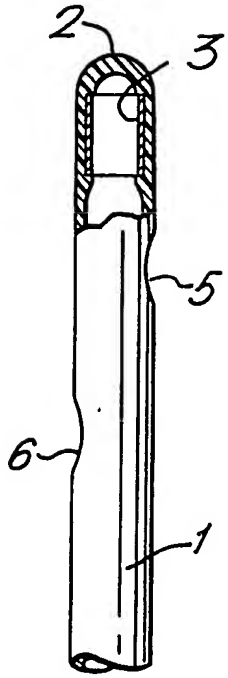

FIG.1.

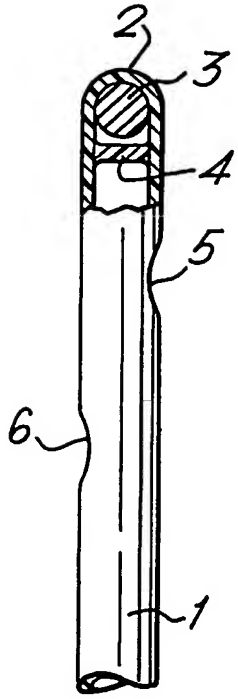

FIG.2.

SPECIFICATION

Improvements in intravascular catheters

This invention relates to intravascular catheters.

It is a common medical procedure to insert a catheter of plastics or elastomeric material into the vascular system, usually percutaneously and advance it from the site of entry to the required distance in order to achieve the purpose required of the catheter. The position of the catheter in the vessel is determined radiographically; failure to detect the tip of the catheter by X-ray has been the cause of fatal accidents when the catheter tip has punctured the heart wall. There have been many serious consequences of the catheter tip perforating the wall of a blood vessel due to over-advancement of the catheter. It is therefore essential that an intravascular catheter can be clearly seen by X-ray.

Conventionally, the material of the catheter has been compounded with a radio-opaque filler, but this measure has given inadequate contrast for certain applications. For instance, when the tip of the catheter enters the large vessels near the heart in order, for example, to record blood or administer fluid, radiography is hindered by tissue. It is the tip of the catheter which is liable to cause damage, and the tip is most deeply overlaid by tissue and thus exhibits the lowest contrast during radiographic examination. There is a limit to the proportion of radio-opaque filler which can be included without adversely affecting the mechanical properties and biological safety of the catheter material. It is easy for the doctor to misinterpret the X-ray image and to imagine that the tip is behind its true position in the patient's body.

It has been proposed, e.g. in U.S. Patent No. 2,978,863, to provide a radio-opaque wire extending down the bore of the catheter along its whole length to enable the catheter to be seen by X-ray and to enable torque to be applied. However the wire considerably increases the stiffness of the catheter and, without highly skilful manipulation, there is an increased risk of advancing the distal end through the wall of a blood vessel and causing serious damage to the patient. For some purposes, e.g. embolectomy, a relatively stiff catheter may be necessary, but for general use a more flexible device is strongly preferred.

The same objections apply to catheters having braided wire incorporated in their wall; such catheters are very dangerous unless the top is guided with great accuracy.

The intravascular catheter of this invention has localised inside the distal tip thereof a radio-opaque metallic component. The metallic component gives excellent X-ray contrast and enables the tip of the catheter to be detected when deep in the thoracic cavity. The remainder of the catheter may not require to be radio opaque and its material can be chosen to give optimal mechanical and biological properties. In some cases the whole catheter may be radio-opaque, to aid location in the event of accidental cutting of the catheter while in the body. Even in this case the metallic component in the tip is a very useful aid to precise positioning of the device during normal use. Suitable materials for the catheter include e.g. PVC, polyurethane and polyethylene.

The metallic component should be sufficiently radio-opaque to give the desired X-ray contrast and preferably should be non-corrodible to avoid any toxicity hazard if the component should unexpectedly come into contact with body fluids. Suitable metals include non-corrodible steel, tungsten and silver.

The metallic component can be of any desired shaped, e.g. spherical, hemispherical, cylindrical, tubular, bullet-shaped or helical. An elongated component can indicate the direction in which the catheter tip is pointing. A tubular component is particularly convenient in manufacture of the catheter.

The metallic component must be immobilised in the tip of the catheter so that it cannot accidentally escape into the vascular system. It is preferred to mould the metallic component into the tip of the catheter. Alternatively it can be immobilised by heat or solvent welding or by an adhesive. The metallic component may be encapsulated in the tip e.g. by an adhesive which preferably has been polymerised in situ, or if sufficiently inert it may be exposed to fluid in the catheter.

Two embodiments of our invention are illustrated by way of example in the accompanying drawings wherein:

Figure 1 shows in partial cross-section of the tip of an intravascular catheter according to the insertion having a preferred tubular metallic component, and

Figure 2 shows in partial cross-section an alternative embodiment having a spherical metallic component.

Referring now to Fig. 1, the catheter 1 is of biologically suitable plastics tubing, e.g. PVC. Immediately behind the tip 2 is a stainless steel cylindrical tube 3 having a diameter of about 1 mm. The tube 3 is moulded into the tip 2 and the tip 2 is closed in the same moulding operation. Two eyes 5 and 6 on opposite sides of the catheter allow for the passage of fluid. In use the tube 3 casts a dense shadow on the screen of a fluoroscope which indicates the precise position of the catheter tip.

In the embodiment of Fig. 2 the metallic component is a stainless steel ball 3 having a diameter of about 1 mm. The ball 3 is locked in position by a piece of PVC mono-filament 4 bonded to the walls of the catheter.

CLAIMS

1. An intravascular catheter of flexible plastics or elastomeric material having localised inside the distal tip thereof a radio-opaque metallic component.

2. A catheter according to claim 1 wherein said metallic component has been moulded into the distal tip of the catheter.

3. A catheter according to claim 1 or 2 wherein said metallic component is tubular.

4. A catheter according to any of the preceding claims wherein said metallic component is of stainless steel.

5. An intravascular catheter substantially as illustrated in Fig. 1 of the accompanying drawings.

6. An intravascular catheter substantially as illustrated in Fig. 2 of the accompanying drawings.

Printed for Her Majesty's Stationery Office
by Burgess & Son (Abingdon) Ltd.—1980.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.